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Attorneys for Defendants  
ORTHO-MCNEIL PHARMACEUTICAL, INC., now  
known as ORTHO-McNEIL-JANSSEN  
PHARMACEUTICALS, INC.,  
and MCKESSON CORPORATION

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

THERESA CLEMONDS, an individual;  
VALERI HAMILTON, an individual;  
CLAUDIA MATAMOROS, an individual;  
LATASHA PRENTICE, an individual;  
MARGARET RAINEY, an individual;  
FELECIA SOUTHWELL, an individual;  
HALEY VANSANDT, an individual;

Plaintiffs,

v.

ORTHO-MCNEIL PHARMACEUTICAL,  
INC., a Delaware Corporation;  
MCKESSON CORP. and DOES 1-500,  
inclusive,

Defendants.

Case No.

**08 1167**  
**DEFENDANTS' ANSWER TO  
COMPLAINT; DEMAND FOR JURY  
TRIAL**

Defendants Ortho-McNeil Pharmaceutical, Inc. ("OMP"), now known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI"), and McKesson Corporation ("McKesson") (collectively "Defendants"), by and through counsel, hereby respond to the allegations set forth in Plaintiffs' Complaint (the "Complaint"), as follows:

**ANSWER TO INTRODUCTION**

1. Defendants are without knowledge or information sufficient to form a belief as to Plaintiffs' allegations that they used ORTHO EVRA®. Defendants deny the

1 remaining allegations contained in paragraph 1 of Plaintiffs' Complaint.

2 2. Defendants admit that OMP, now known as OMPJI, manufactured,  
3 advertised, promoted, marketed, sold and distributed ORTHO EVRA®. Defendants deny  
4 the remaining allegations contained in paragraph 2 of Plaintiffs' Complaint.

5 3. Defendants admit that McKesson is a non-exclusive distributor of ORTHO  
6 EVRA® and has its principal place of business in San Francisco, California. Defendants  
7 deny the remaining allegations contained in paragraph 3 of Plaintiffs' Complaint.

8 4. Defendants admit that on the ORTHO EVRA® Web site, it stated that:  
9 "The transdermal -- or 'through the skin' -- weekly birth control patch prevents  
10 pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl  
11 estradiol (progestin and estrogen, respectively) through the skin and into the  
12 bloodstream." Defendants admit that the FDA approved the use of ORTHO EVRA® for  
13 the prevention of pregnancy in November 2001. Defendants further admit that the FDA's  
14 publications state what they state. Defendants deny the remaining allegations contained  
15 in paragraph 4 of Plaintiffs' Complaint.

16 **ANSWER TO JURISDICTION AND VENUE**

17 5. Paragraph 5 of Plaintiffs' Complaint contains legal conclusions to which no  
18 response is required.

19 6. Defendants admit that OMP, now known as OMPJI, was a Delaware  
20 corporation with its principal place of business in New Jersey, that OMPJI is a  
21 Pennsylvania corporation with its principal place of business in New Jersey, and that  
22 McKesson is a Delaware corporation with its principal place of business in California.  
23 Defendants deny the remaining allegations contained in paragraph 6 of Plaintiffs'  
24 Complaint.

25 7. Defendants admit that McKesson has its principal place of business in San  
26 Francisco, California. Defendants deny the remaining allegations contained in paragraph  
27 7 of Plaintiffs' Complaint.

28 8. Defendants admit that McKesson has its principal place of business in San

1 Francisco, California. Defendants deny the remaining allegations contained in paragraph  
2 8 of Plaintiffs' Complaint.

3 9. Defendants are without knowledge or information sufficient to form a  
4 belief as to the allegations contained in paragraph 9 of Plaintiffs' Complaint.

5 **ANSWER TO PLAINTIFFS**

6 10. Defendants are without knowledge or information sufficient to form a  
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 10  
9 of Plaintiffs' Complaint.

10 11. Defendants are without knowledge or information sufficient to form a  
11 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
12 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 11  
13 of Plaintiffs' Complaint.

14 12. Defendants are without knowledge or information sufficient to form a  
15 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
16 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 12  
17 of Plaintiffs' Complaint.

18 13. Defendants are without knowledge or information sufficient to form a  
19 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
20 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 13  
21 of Plaintiffs' Complaint.

22 14. Defendants are without knowledge or information sufficient to form a  
23 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
24 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 14  
25 of Plaintiffs' Complaint.

26 15. Defendants are without knowledge or information sufficient to form a  
27 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
28 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 15

1 of Plaintiffs' Complaint.

2 16. Defendants are without knowledge or information sufficient to form a  
3 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
4 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 16  
5 of Plaintiffs' Complaint.

6 **ANSWER TO DEFENDANTS**

7 17. Defendants admit that OMP, now known as OMPJI, was a Delaware  
8 corporation with its principal place of business in New Jersey and that OMPJI is a  
9 Pennsylvania corporation with its principal place of business in New Jersey. Defendants  
10 deny the remaining allegations contained in paragraph 17 of Plaintiffs' Complaint.

11 18. Defendants admit that OMP, now known as OMPJI, conducts business in  
12 California. Defendants deny the remaining allegations contained in paragraph 18 of  
13 Plaintiffs' Complaint.

14 19. Defendants are without knowledge or information sufficient to form a  
15 belief as to the allegations contained in paragraph 19 of Plaintiffs' Complaint, and  
16 therefore these allegations are denied.

17 20. Defendants are without knowledge or information sufficient to form a  
18 belief as to the allegations contained in paragraph 20 of Plaintiffs' Complaint, and  
19 therefore these allegations are denied.

20 21. Defendants admit that OMP, now known as OMPJI, manufactured,  
21 marketed, promoted, sold and distributed ORTHO EVRA®. Defendants deny the  
22 remaining allegations contained in paragraph 21 of Plaintiffs' Complaint.

23 22. Defendants admit that McKesson is a Delaware corporation with its  
24 principal place of business in San Francisco, California. Defendants further admit that  
25 McKesson conducts business in California. Defendants deny the remaining allegations  
26 contained in paragraph 22 of Plaintiffs' Complaint.

27 22. Defendants are without knowledge or information sufficient to form a  
28 belief as to the allegations contained in paragraph 23 of Plaintiffs' Complaint, and



1 therefore these allegations are denied.

2 24. Defendants are without knowledge or information sufficient to form a  
3 belief as to the allegations contained in paragraph 24 of Plaintiffs' Complaint, and  
4 therefore these allegations are denied.

5 25. Defendants admit that McKesson is a non-exclusive distributor of ORTHO  
6 EVRA®. Defendants deny the remaining allegations contained in paragraph 25 of  
7 Plaintiffs' Complaint.

8 26. Defendants are without knowledge or information sufficient to form a  
9 belief as to the allegations contained in paragraph 26 of Plaintiffs' Complaint.

10 27. Defendants are without knowledge or information sufficient to form a  
11 belief as to the allegations contained in paragraph 27 of Plaintiffs' Complaint.

12 28. To the extent that paragraph 28 of Plaintiffs' Complaint alleges improper  
13 conduct on the part of Defendants, such allegations are denied.

14 29. To the extent that paragraph 29 of Plaintiffs' Complaint alleges improper  
15 conduct on the part of Defendants, such allegations are denied.

16 **ANSWER TO GENERAL ALLEGATIONS**

17 30. OMP, now known as OMPJI, admits that on the OMP Web site, it stated  
18 that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in  
19 women's health care. Ortho-McNeil offers the broadest range of prescription birth  
20 control options..." OMP, now known as OMPJI, further admits that it manufactures and  
21 sells ORTHO EVRA®, the first combination transdermal contraceptive patch.  
22 Defendants deny the remaining allegations contained in paragraph 30 of Plaintiffs'  
23 Complaint.

24 31. OMP, now known as OMPJI, admits that ORTHO EVRA® is the first and  
25 only once-a-week birth control patch. OMP, now known as OMPJI, further admits that  
26 on the ORTHO EVRA® Web site, it stated that: "The transdermal -- or 'through the skin'  
27 -- weekly birth control patch prevents pregnancy by delivering continuous levels of the  
28 hormones norelgestromin and ethinyl estradiol (progestin and estrogen, respectively)

1 through the skin and into the bloodstream." Defendants deny the remaining allegations  
2 contained in paragraph 31 of Plaintiffs' Complaint.

3 32. Defendants admit that a New Drug Application ("NDA") was filed for  
4 ORTHO EVRA®, denoted as 21-180, with the FDA in December 2000. Defendants  
5 further admit that the FDA Medical Officer's Review for ORTHO EVRA® states what it  
6 states. Defendants deny the remaining allegations contained in paragraph 32 of  
7 Plaintiffs' Complaint.

8 33. Defendants admit that the FDA approved the use of ORTHO EVRA® for  
9 the prevention of pregnancy in November 2001. Defendants deny the remaining  
10 allegations contained in paragraph 33 of Plaintiffs' Complaint.

11 34. Defendants admit that as with all prescription medicine, adverse events are  
12 reported to the FDA by a variety of people and entities. Defendants deny the remaining  
13 allegations contained in paragraph 34 of Plaintiffs' Complaint.

14 35. Defendants admit that the FDA's publications state what they state.  
15 Defendants deny the remaining allegations contained in paragraph 35 of Plaintiffs'  
16 Complaint.

17 36. Defendants admit that the November 2005 package insert for ORTHO  
18 EVRA® states what it states. To the extent that paragraph 36 of Plaintiffs' Complaint  
19 alleges improper conduct on the part of Defendants, such allegations are denied.

20 37. OMP, now known as OMPJI, admits that ORTHO EVRA® is the first and  
21 only once-a-week birth control patch. Defendants deny the remaining allegations  
22 contained in paragraph 37 of Plaintiffs' Complaint.

23 38. Defendants deny the allegations contained in paragraph 38 of Plaintiffs'  
24 Complaint.

25 39. Defendants admit that the package insert for ORTHO EVRA® states what  
26 it states. To the extent that paragraph 39 of Plaintiffs' Complaint alleges improper  
27 conduct on the part of Defendants, such allegations are denied.

28 40. Defendants deny the allegations contained in paragraph 40 of Plaintiffs'

1 Complaint.

2 41. Defendants state that they were subject only to those duties imposed by  
3 applicable law, and deny the allegations contained in paragraph 41 of Plaintiffs'  
4 Complaint to the extent they suggest any different or greater duties. Defendants further  
5 deny that they failed to abide by any applicable legal duties.

6 42. Defendants deny the allegations contained in paragraph 42 of Plaintiffs'  
7 Complaint.

8 43. Defendants deny the allegations contained in paragraph 43 of Plaintiffs'  
9 Complaint.

10 44. Defendants deny the allegations contained in paragraph 44 of Plaintiffs'  
11 Complaint.

12 45. Defendants deny the allegations contained in paragraph 45 of Plaintiffs'  
13 Complaint.

14 **ANSWER TO FRAUDULENT CONCEALMENT**

15 46. Defendants deny the allegations contained in paragraph 46 of Plaintiffs'  
16 Complaint.

17 47. Defendants state that they were subject only to those duties imposed by  
18 applicable law, and deny the allegations contained in paragraph 47 of Plaintiffs'  
19 Complaint to the extent they suggest any different or greater duties. Defendants further  
20 deny that they failed to abide by any applicable legal duties, and deny the remaining  
21 allegations contained in this paragraph.

22 **ANSWER TO FIRST CAUSE OF ACTION**

23 **NEGLIGENCE**

24 48. Defendants repeat their answers to the allegations of paragraphs 1 through  
25 47 of Plaintiffs' Complaint as if set forth at length herein.

26 49. Defendants state that they were subject only to those duties imposed by  
27 applicable law, and deny the allegations contained in paragraph 49 of the First Cause of  
28 Action of Plaintiffs' Complaint to the extent they suggest any different or greater duties.

1 Defendants further deny that they failed to abide by any applicable legal duties.

2 50. Defendants deny the allegations contained in paragraph 50 of the First  
3 Cause of Action of Plaintiffs' Complaint.

4 51. Defendants deny the allegations contained in paragraph 51 of the First  
5 Cause of Action of Plaintiffs' Complaint.

6 52. Defendants deny the allegations contained in paragraph 52 of the First  
7 Cause of Action of Plaintiffs' Complaint.

8 53. Defendants deny the allegations contained in paragraph 53 of the First  
9 Cause of Action of Plaintiffs' Complaint.

10 54. Defendants deny the allegations contained in paragraph 54 of the First  
11 Cause of Action of Plaintiffs' Complaint.

12 55. Defendants deny the allegations contained in paragraph 55 of the First  
13 Cause of Action of Plaintiffs' Complaint.

14 56. Defendants deny the allegation that ORTHO EVRA® is defective, and  
15 deny the remaining allegations contained in paragraph 56 of the First Cause of Action of  
16 Plaintiffs' Complaint.

17 57. Defendants deny the allegations contained in paragraph 57 of the First  
18 Cause of Action of Plaintiffs' Complaint.

19 58. Defendants deny the allegations contained in paragraph 58 of the First  
20 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
21 the unnumbered paragraph following paragraph 58.

22 **ANSWER TO SECOND CAUSE OF ACTION**

23 **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

24 59. Defendants repeat their answers to the allegations of paragraphs 1 through  
25 58 of Plaintiffs' Complaint as if set forth at length herein.

26 60. Defendants admit that OMP, now known as OMPJI, manufactures and  
27 supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in  
28 paragraph 60 of the Second Cause of Action of Plaintiffs' Complaint.



1           61. Defendants admit that OMP, now known as OMPJI, manufactures and  
2 supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in  
3 paragraph 61 of the Second Cause of Action of Plaintiffs' Complaint.

4           62. Defendants deny the allegations contained in paragraph 62 of the Second  
5 Cause of Action of Plaintiffs' Complaint.

6           63. Defendants deny the allegation that ORTHO EVRA® is defective, and  
7 deny the remaining allegations contained in paragraph 63 of the Second Cause of Action  
8 of Plaintiffs' Complaint.

9           64. Defendants deny the allegation that ORTHO EVRA® is defective, and  
10 deny the remaining allegations contained in paragraph 64 of the Second Cause of Action  
11 of Plaintiffs' Complaint.

12           65. Defendants deny the allegations contained in paragraph 65 of the Second  
13 Cause of Action of Plaintiffs' Complaint.

14           66. Defendants deny the allegation that ORTHO EVRA® is defective, and  
15 deny the remaining allegations contained in paragraph 66 of the Second Cause of Action  
16 of Plaintiffs' Complaint.

17           67. Defendants deny the allegations contained in paragraph 67 of the Second  
18 Cause of Action of Plaintiffs' Complaint.

19           68. Defendants deny the allegations contained in paragraph 68 of the Second  
20 Cause of Action of Plaintiffs' Complaint.

21           69. Defendants deny the allegations contained in paragraph 69 of the Second  
22 Cause of Action of Plaintiffs' Complaint.

23           70. Defendants deny the allegations contained in paragraph 70 of the Second  
24 Cause of Action of Plaintiffs' Complaint.

25           71. Defendants deny the allegations contained in paragraph 71 of the Second  
26 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
27 the unnumbered paragraph following paragraph 71.  
28

**ANSWER TO THIRD CAUSE OF ACTION  
BREACH OF EXPRESS WARRANTY**

72. Defendants repeat their answers to the allegations of paragraphs 1 through 71 of Plaintiffs' Complaint as if set forth at length herein.

73. Defendants deny the allegations contained in paragraph 73 of the Third Cause of Action of Plaintiffs' Complaint.

74. Defendants deny the allegations contained in paragraph 74 of the Third Cause of Action of Plaintiffs' Complaint.

75. Defendants deny the allegations contained in paragraph 75 of the Third Cause of Action of Plaintiffs' Complaint.

76. Defendants deny the allegations contained in paragraph 76 of the Third Cause of Action of Plaintiffs' Complaint.

77. Defendants deny the allegations contained in paragraph 77 of the Third Cause of Action of Plaintiffs' Complaint.

78. Defendants deny the allegations contained in paragraph 78 of the Third Cause of Action of Plaintiffs' Complaint.

79. Defendants deny the allegations contained in paragraph 79 of the Third Cause of Action of Plaintiffs' Complaint.

80. Defendants deny the allegations contained in paragraph 80 of the Third Cause of Action of Plaintiffs' Complaint.

81. Defendants deny the allegations contained in paragraph 81 of the Third Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 81.

**ANSWER TO FOURTH CAUSE OF ACTION  
BREACH OF IMPLIED WARRANTY**

82. Defendants repeat their answers to the allegations of paragraphs 1 through 81 of Plaintiffs' Complaint as if set forth at length herein.

83. Defendants admit that OMP, now known as OMPJI, marketed, sold and

1 distributed ORTHO EVRA®, which is used for the prevention of pregnancy. Defendants  
2 further admit that McKesson is a non-exclusive distributor of ORTHO EVRA®, and  
3 deny that McKesson marketed or sold ORTHO EVRA®. The remainder of paragraph 83  
4 of the Fourth Cause of Action of Plaintiffs' Complaint contains a legal conclusion to  
5 which no response is required.

6 84. Paragraph 84 of the Fourth Cause of Action of Plaintiffs' Complaint  
7 contains legal conclusions to which no response is required.

8 85. Defendants are without knowledge or information sufficient to form a  
9 belief as to the allegations contained in paragraph 85 of the Fourth Cause of Action of  
10 Plaintiffs' Complaint, and therefore these allegations are denied.

11 86. Defendants deny the allegations contained in paragraph 86 of the Fourth  
12 Cause of Action of Plaintiffs' Complaint.

13 87. Defendants deny the allegations contained in paragraph 87 of the Fourth  
14 Cause of Action of Plaintiffs' Complaint.

15 88. Defendants deny the allegations contained in paragraph 88 of the Fourth  
16 Cause of Action of Plaintiffs' Complaint.

17 89. Defendants deny the allegations contained in paragraph 89 of the Fourth  
18 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
19 the unnumbered paragraph following paragraph 89.

20 **ANSWER TO FIFTH CAUSE OF ACTION**

21 **NEGLIGENT MISREPRESENTATION**

22 90. Defendants repeat their answers to the allegations of paragraphs 1 through  
23 89 of Plaintiffs' Complaint as if set forth at length herein.

24 91. Defendants admit that OMP, now known as OMPJI, manufactures,  
25 markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were  
26 subject only to those duties imposed by applicable law, and deny the allegations  
27 contained in this paragraph to the extent they suggest any different or greater duties.  
28 Defendants further deny that they failed to abide by any applicable legal duties, and deny

1 the remaining allegations contained in paragraph 91 of the Fifth Cause of Action of  
2 Plaintiffs' Complaint.

3 92. Defendants deny the allegations contained in paragraph 92 of the Fifth  
4 Cause of Action of Plaintiffs' Complaint.

5 93. Defendants deny the allegations contained in paragraph 93 of the Fifth  
6 Cause of Action of Plaintiffs' Complaint.

7 94. Defendants deny the allegations contained in paragraph 94 of the Fifth  
8 Cause of Action of Plaintiffs' Complaint.

9 95. Defendants deny the allegations contained in paragraph 95 of the Fifth  
10 Cause of Action of Plaintiffs' Complaint.

11 96. Defendants deny the allegations contained in paragraph 96 of the Fifth  
12 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
13 the unnumbered paragraph following paragraph 96.

#### 14 **ANSWER TO SIXTH CAUSE OF ACTION**

##### 15 **FRAUD**

16 97. Defendants repeat their answers to the allegations of paragraphs 1 through  
17 96 of Plaintiffs' Complaint as if set forth at length herein.

18 98. Defendants admit that OMP, now known as OMPJI, manufactures,  
19 markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were  
20 subject only to those duties imposed by applicable law, and deny the allegations  
21 contained in this paragraph to the extent they suggest any different or greater duties.  
22 Defendants further deny that they failed to abide by any applicable legal duties, and deny  
23 the remaining allegations contained in paragraph 98 of the Sixth Cause of Action of  
24 Plaintiffs' Complaint.

25 99. Defendants deny the allegations contained in paragraph 99 of the Sixth  
26 Cause of Action of Plaintiffs' Complaint.

27 100. Defendants deny the allegations contained in paragraph 100 of the Sixth  
28 Cause of Action of Plaintiffs' Complaint.



1 101. Defendants deny the allegations contained in paragraph 101 of the Sixth  
2 Cause of Action of Plaintiffs' Complaint.

3 102. Defendants deny the allegations contained in paragraph 102 of the Sixth  
4 Cause of Action of Plaintiffs' Complaint.

5 103. Defendants deny the allegations contained in paragraph 103 of the Sixth  
6 Cause of Action of Plaintiffs' Complaint.

7 104. Defendants deny the allegations contained in paragraph 104 of the Sixth  
8 Cause of Action of Plaintiffs' Complaint.

9 105. Defendants deny the allegations contained in paragraph 105 of the Sixth  
10 Cause of Action of Plaintiffs' Complaint.

11 106. Defendants are without knowledge or information sufficient to form a  
12 belief as to Plaintiffs' states of mind. Defendants deny the remaining allegations  
13 contained in paragraph 106 of the Sixth Cause of Action of Plaintiffs' Complaint.

14 107. Defendants deny the allegations contained in paragraph 107 of the Sixth  
15 Cause of Action of Plaintiffs' Complaint.

16 108. Defendants deny the allegations contained in paragraph 108 of the Sixth  
17 Cause of Action of Plaintiffs' Complaint.

18 109. Defendants deny the allegations contained in paragraph 109 of the Sixth  
19 Cause of Action of Plaintiffs' Complaint.

20 110. Defendants deny the allegations contained in paragraph 110 of the Sixth  
21 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
22 the unnumbered paragraph following paragraph 110.

23 **FIRST AFFIRMATIVE DEFENSE**

24 Plaintiffs' Complaint fails to state a claim against Defendants upon which relief  
25 may be granted.

26 **SECOND AFFIRMATIVE DEFENSE**

27 Venue is improper in this court.  
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**THIRD AFFIRMATIVE DEFENSE**

Plaintiffs are fraudulently joined and/or misjoined, and the court should sever Plaintiffs' claims and/or enter other appropriate orders to avoid prejudice, unfairness, hardship, delay, and undue expense and to promote convenience and expedience.

**FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, to the extent certain Plaintiffs have asserted duplicative claims in one or more other actions pending against some or all of the same defendants.

**FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the applicable statute of limitations, statute of repose and/or by the equitable doctrines of laches and estoppel.

**SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the doctrines of informed consent, release and waiver.

**SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred because the alleged damages, if any are proven, were not proximately caused by any act or omission of any of the Defendants.

**EIGHTH AFFIRMATIVE DEFENSE**

If Plaintiffs suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were a direct and proximate result of a responsible, superseding, and/or intervening cause.

**NINTH AFFIRMATIVE DEFENSE**

Defendants state that if Plaintiffs have suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident or preexisting condition, without any

1 negligence and culpable conduct by Defendants.

2  
3 **TENTH AFFIRMATIVE DEFENSE**

4 Plaintiffs' injuries and damages, if any, were caused in whole or in part by the acts  
5 (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration,  
6 omission or fault of one or more persons or entities over whom Defendants exercised no  
7 control and for whom Defendants are not legally responsible, including, without  
8 limitation, Plaintiffs.

9 **ELEVENTH AFFIRMATIVE DEFENSE**

10 Plaintiffs failed to exercise reasonable care and diligence to mitigate injuries and  
11 damages, if any.

12 **TWELFTH AFFIRMATIVE DEFENSE**

13 Plaintiffs' claims are barred by the "state of the art" and "state of scientific  
14 knowledge" defenses.

15 **THIRTEENTH AFFIRMATIVE DEFENSE**

16 Plaintiffs' claims are barred by the Learned Intermediary Doctrine.

17 **FOURTEENTH AFFIRMATIVE DEFENSE**

18 The product at issue in this case falls under the auspices of the Food, Drug and  
19 Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration,  
20 and therefore, Federal law preempts Plaintiffs' claims. *See*, 21 U.S.C. §301 *et. seq.* *See*  
21 *also*, 71 Fed. Reg. 3922 (January 24, 2006).

22 **FIFTEENTH AFFIRMATIVE DEFENSE**

23 Defendants did not make to Plaintiffs nor did they breach any express or implied  
24 warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely  
25 on any theory of breach of warranty, such claims are barred by applicable law, and for  
26 lack of privity with Defendants and/or for failure of Plaintiffs, or Plaintiffs'  
27 representatives, to give timely notice to Defendants of any alleged breach of warranty.  
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1 Plaintiffs did not rely on any alleged warranty. Defendants further specifically plead as  
2 to any breach of warranty claim all affirmative defenses under the Uniform Commercial  
3 Code existing and which may arise in the future, as enacted in the State of California, and  
4 any other state whose law is deemed to apply in this case.

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6 **SIXTEENTH AFFIRMATIVE DEFENSE**

7 Plaintiffs' claims are barred by comments j and k to Section 402A of the  
8 Restatement (Second) of Torts.

9 **SEVENTEENTH AFFIRMATIVE DEFENSE**

10 Plaintiffs' claims of product defects are barred by Section 2, 4, and 6(c) and (d) of  
11 the Restatement (Third) of Torts: Products Liability.

12 **EIGHTEENTH AFFIRMATIVE DEFENSE**

13 Plaintiffs' product liability claims are barred because the benefits of the relevant  
14 product outweighed its risks.

15 **NINETEENTH AFFIRMATIVE DEFENSE**

16 Plaintiffs' claims are barred in whole or part because the product at issue was at all  
17 times properly prepared, packaged, and distributed, and was not defective or  
18 unreasonably dangerous.

19 **TWENTIETH AFFIRMATIVE DEFENSE**

20 Any imposition of punitive damages in this case against Defendants is barred to  
21 the extent that the manner in which such punitive damages are calculated violates the  
22 Constitution of the United States or the Constitution of the State of California.

23 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

24 Any award of punitive damages in this case against Defendants is barred to the  
25 extent that the amount of such an award violates the Constitution of the United States or  
26 the Constitution of the State of California.  
27  
28



**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs have failed to plead fraud with specificity.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Defendants are entitled to a setoff for all amounts paid, payable by or available from collateral sources.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

The Complaint fails to state a cause of action against Defendants because there is no private right of action under the applicable federal law. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to *Buckman v. Plaintiffs' Legal Community*, 531 U.S. 341 (2001).

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue, barring in whole or in part the damages Plaintiffs seek to recover.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

In the event Defendants, or any of them, are held liable to Plaintiffs, or any of them, which liability is expressly denied, or a settlement of judgment against Defendants, or any of them, is reached, Defendants request an apportionment of fault be made as permitted by *Li v. Yellow Cab Company*, 13 Cal.3d 804 (1975) and *American Motorcycle Association v. Superior Court*, 20 Cal.3d 578 (1987) and a judgment and declaration of indemnification and contribution be entered against all other persons and entities in accordance with that apportionment of fault.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

The amount of any award on behalf of Plaintiffs, or any of them, for non-economic loss must be allocated according to the provisions of California Civil Code Section 1431.2 ("Proposition 51").

**TWENTY- EIGHTH AFFIRMATIVE DEFENSE**

Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional facts are obtained.

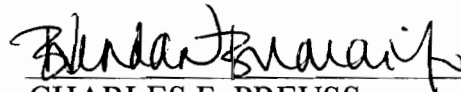
WHEREFORE, having fully answered, Defendants specifically controvert Plaintiffs' Prayer for Relief including Paragraphs (1)-(6).

**JURY DEMAND**

Defendants hereby demand a trial by jury of all the facts and issues in this case pursuant to Federal Rule of Civil Procedure 38(b).

Dated: February 26, 2008

DRINKER BIDDLE & REATH



CHARLES F. PREUSS

BRENDA N. BUONAIUTO

Attorneys for Defendants

ORTHO-MCNEIL PHARMACEUTICAL,  
INC., now known as ORTHO-MCNEIL-  
JANSSEN PHARMACEUTICALS, INC.,  
and MCKESSON CORPORATION